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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/34

A1

(11) International Publication Number: WO 00/54676

(43) International Publication Date: 21 September 2000 (21.09.00)

(21) International Application Number: PCT/IE00/00033

(22) International Filing Date: 20 March 2000 (20.03.00)

(30) Priority Data:
S990220 18 March 1999 (18.03.99) IE

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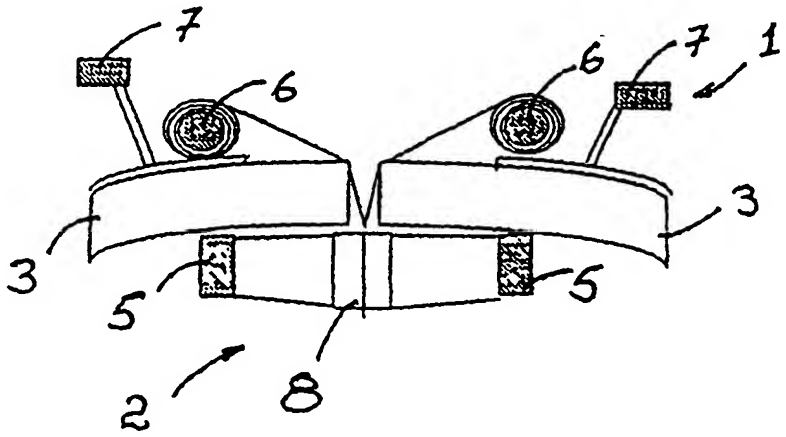
(81) Designated States: CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A SURGICAL ACCESS DEVICE



(57) Abstract

Surgical device (1) is for use in minimally invasive surgery using an inflated body cavity (2) accessible to a surgeon through an access port defined by a sleeve (4) passing through an incision in a patient's abdominal wall (3). The device is held in position by a distal ring (5) and a proximal ring (6). The device (1) is sealed by cuff valve (8), self sealing valve (18), spring valve (28) or snap open/snap shut valve (38).

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A SURGICAL ACCESS DEVICE

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patient's abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

There is therefore a need for a surgical device, which will overcome the aforementioned problems.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin;

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

Preferably, the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

In one arrangement, the distal ring has an associated cuff valve operating on the internal faces of an impermeable film, the film being located between semi rigid actuates, the actuates in turn being secured in substantially parallel manner to a distal ends of the sleeve.

Preferably the actuates are housed in opposing cuff, each cuff being formed by folding an end of a distal tube to form a pocket for reception of the actuate.

Ideally the actuates incorporate a bio-compatible medical grade foam layer to generate tension between opposing faces of the film and to operate as a cushion between the actuates and objects inserted through the cuff valve.

In an alternative arrangement, the distal ring has an associated self-sealing valve.

Preferably, the fixing means is provided by a proximal ring for engaging with a patient's skin.

In one arrangement the fixing means incorporates adjustment means for modifying the length of the sleeve. This ensures that the fixing means, distal ring and valves are brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device is firmly mounted in position.

In one arrangement, the proximal ring has an associated connector ring for receiving additional seals or medical instruments.

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, some embodiments of a surgical device in accordance with the invention, in which: -

Fig. 1 is a front view of a surgical device in accordance with the invention;

Fig. 2 is a section view in the direction of the arrows A-A of the surgical device of Fig. 1;

Fig. 3 is an end view of the surgical device of Figs. 1 and 2;

Fig. 4 is a side view of an alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;

Fig. 5 is a side view of portion of the valve shown in Fig. 4 in an operating position;

Fig. 6 is a side view of a further alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;

Fig. 7 is a side view of portion of the valve shown in Fig. 6 in an operating position;

Fig. 8 is a side view of another self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position; and

Fig. 9 is a side view of portion of the valve shown in Fig. 8 in an operating position.

Referring to the drawings, and initially to Figs. 1 to 3 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity indicated generally by the reference numeral 2. The cavity 2 is accessible to a surgeon through an access port, defined by a sleeve 4, passing through an incision in a patient's abdominal wall 3.

In more detail, the device 1 has a body cavity engagement means provided by a distal ring 5 for insertion into the incision to locate the device 1 in position. The distal ring 5 prevents the device from becoming detached from the body inadvertently and has an associated cuff valve 8 for sealing the sleeve 4 when in not in use. The device 1 is held in position on the patient's skin out side the body by a fixing means provided in this case by a proximal ring 6. The distal ring 5 and proximal ring 6 ensure that the device 1 is securely fixed in position, both rings 5,6 surround the incision and the sleeve 4 passes through the incision connecting the rings 5 and 6. The proximal ring 6 has adjustment means provided by being rotatably mounted on the skin to modify the length of the sleeve 4. This ensures that the fixing means and the distal ring 5 are brought into close contact with the abdominal wall 3 thereby, ensuring a good seal is maintained and that the device 1 is firmly mounted in position.

The proximal ring 6 may have a connector ring 7 for receiving additional seals to prevent loss of pressure from the cavity 2. The connector ring 7 may also be used for holding or guiding medical instruments into position over, through or in the incision.

In use, an incision is made in the abdominal wall 3 and the distal ring 5 and associated cuff valve 8 is passed through the incision into the cavity 2. The cuff valve 8 operates by pressing together internal faces of a flexible gas impermeable film mounted between semi-rigid actuates. The actuates are arranged substantially parallel in folded ends of a distal tube forming pockets to hold them in tension. The actuates have a bio-compatible medical grade foam along a side to cause tension between opposing faces of the film and to act as a cushion for objects inserted into the valve. The distal ring 5 is moved when in the cavity 2 so that the ring 5 surrounds the incision. The distal ring 5 thus surrounds the cuff valve 8. The proximal ring 6 can then be rotated, adjusted in height or stretched to take up the material and surplus sleeve 4 on the proximal ring 6. When the distal ring 5 is drawn up to snugly engage the internal abdominal wall 3 surrounding the incision, the proximal ring 6 is attached to the patient's skin to fix the device 1 in position. When in position, the sleeve 4 passing between the portions of the abdominal wall 3 exposed by the incision retracts the incision sides creating a lumen or bore through which an object or hand can be passed. A seal is provided by the cuff valve 8.

When a surgeon wishes to gain access to the cavity 2 a hand or instrument is passed down through the sleeve 4. The outward pressure of the retracted sleeve 4 on the abdominal wall ensures that access is not restricted. The cuff valve 8 is easily operated by the surgeon to gain access to the cavity 2 and surgery can be performed. As an object is removed, the cuff valve 8 closes down sealing the cavity 2.

It will be noted that equivalent methods of dispensing and retracting slack sleeve material following positioning of the device may be used.

Alternative embodiments of the invention are now described in which the cuff valve is replaced with a variety of self-sealing valves, however, it will be understood that the operation of these valves is not dependent on the adjustment means described above.

Referring now to Figs. 4 and 5 there is illustrated a further surgical device in accordance with the invention indicated generally by the reference numeral 20, in which parts similar to those identified with reference to Figs. 1 to 3 are identified by the same reference numerals generally. In this embodiment the cuff valve 8 has been replaced by a self-sealing valve 18. The valve 18 incorporates elasticised filaments, which are biased toward a closed position or inoperative position (see Fig. 4). When a surgeon passes a hand or instrument between the filaments which run all around the end of the sleeve 4 they are forced out of position into an operating position as shown in Fig. 5. As filaments are used they accurately mould to the surface of the inserted object preventing loss of gas from the body cavity 2. The memory resident in these filaments returns the valve 18 to the inoperative position once the object is removed to re-seal the sleeve 4.

Figs. 6 and 7 show an alternative to the cuff valve 8 described above in relation to Figs. 1 to 3. In this alternative embodiment, a spring valve 28 provides the seal to the sleeve 4. The spring valve 28 is provided by mounting a member 27 within a pocket 29 of the sleeve 4. Tension in the spring valve 28 is provided by forming the member 27 to be longer that the pocket 29. Operation of this valve is identical to that described above.

A further alternative valve is shown in Figs. 8 and 9. In this embodiment the horseshoe valve is provided as a snap open / snap shut valve 38. When positioned as described above the valve 38 is actuated by a surgeons hand or instrument to open or close the valve 38, by pivoting springed members about a pivot point 39 between an operating position as shown in Fig. 8 and an inoperative position as shown in Fig. 9. The method of biasing the members may be provided in any suitable way and the closing pressure is such as to avoid damage to any tissue, which may become trapped.

A still further arrangement, the proximal ring may be adjusted in height by means of inserting compressible foam rings between the proximal ring and the abdominal wall.

Alternatively, the sleeve may be made of an elastomer material which when the distal ring is inserted into the incision, stretches the elastomer sheet causing tension between the distal ring and the proximal ring.

It will be understood that the self-sealing valves described herein may be equally used as external proximal valves or as internal distal valves.

It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention.

CLAIMS:

1. A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin;

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

2. A surgical device as claimed in Claim 1 in which the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

3. A surgical device as claimed in Claim 2, in which the distal ring has an associated cuff valve operating on the internal faces of an impermeable film, the film being located between semi rigid actuates, the actuates in turn being secured in substantially parallel manner to a distal ends of the sleeve.

4. A surgical device as claimed in Claim 3, in which the actuates are housed in opposing cuff, each cuff being formed by folding an end of a distal tube to form a pocket for reception of the actuate.

5. A surgical device as claimed in Claim 3 or Claim 4, in which the actuates incorporate a bio-compatible medical grade foam layer to generate tension between opposing faces of the film and to operate as a cushion between the actuates and objects inserted through the cuff valve.

6. A surgical device as claimed in Claim 2, in which the distal ring has an associated self-sealing valve.

7. A surgical device as claimed in any one of the preceding claims, in which the fixing means is provided by a proximal ring for engaging with a patient's skin.

8. A surgical device as claimed in Claim 6, in which the fixing means incorporates adjustment means for modifying the length of the sleeve, so as to ensure that the fixing means, distal ring and valves may be brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device is firmly mounted in position.

9. A surgical device as claimed in Claim 7, in which the proximal ring has an associated connector ring for receiving additional seals or medical instruments.

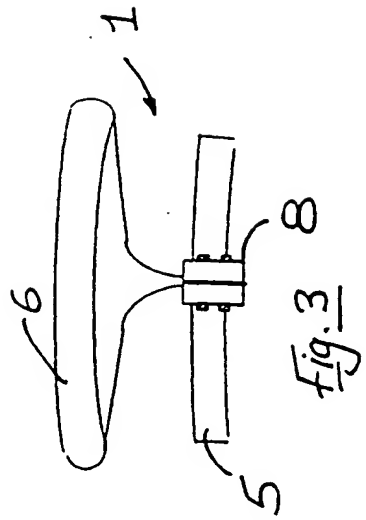

Fig. 3

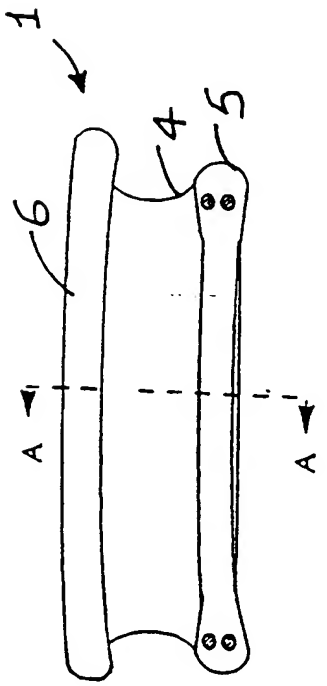

Fig. 1

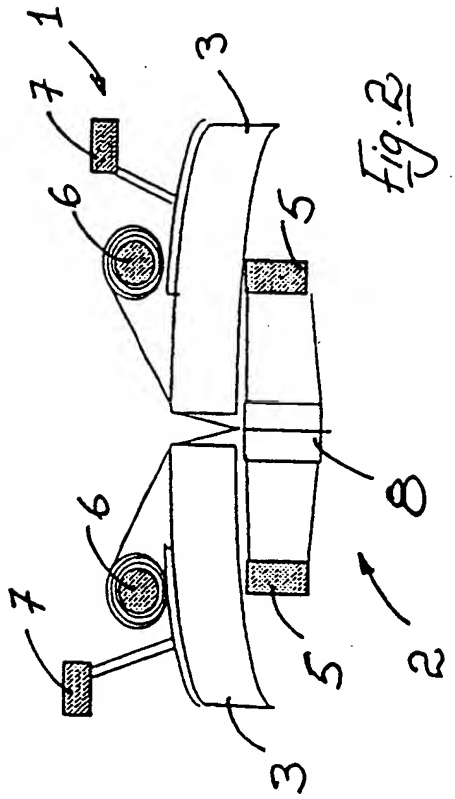

Fig. 2

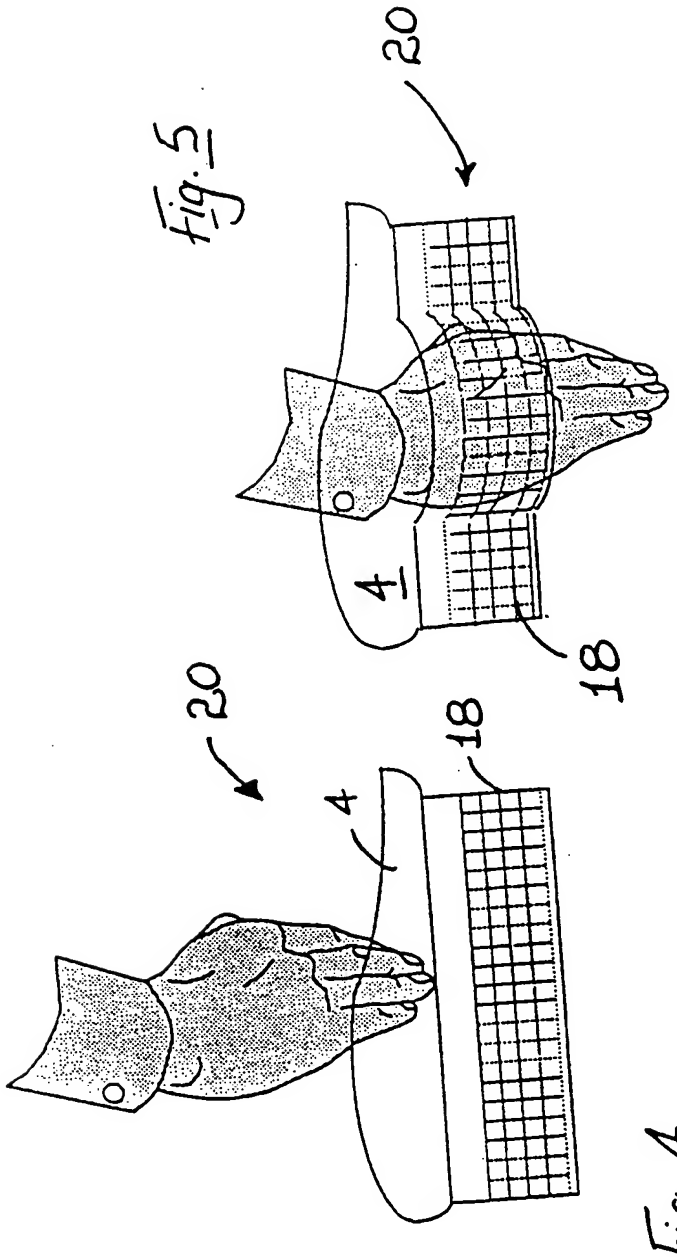

Fig. 5

Fig. 4

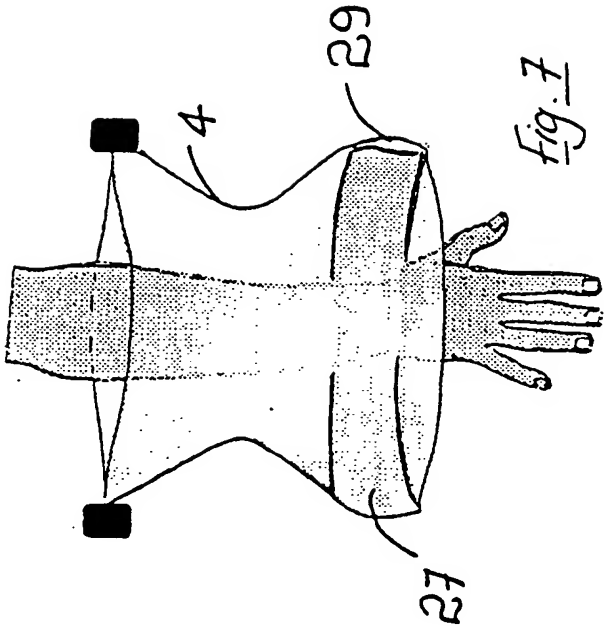

Fig. 7

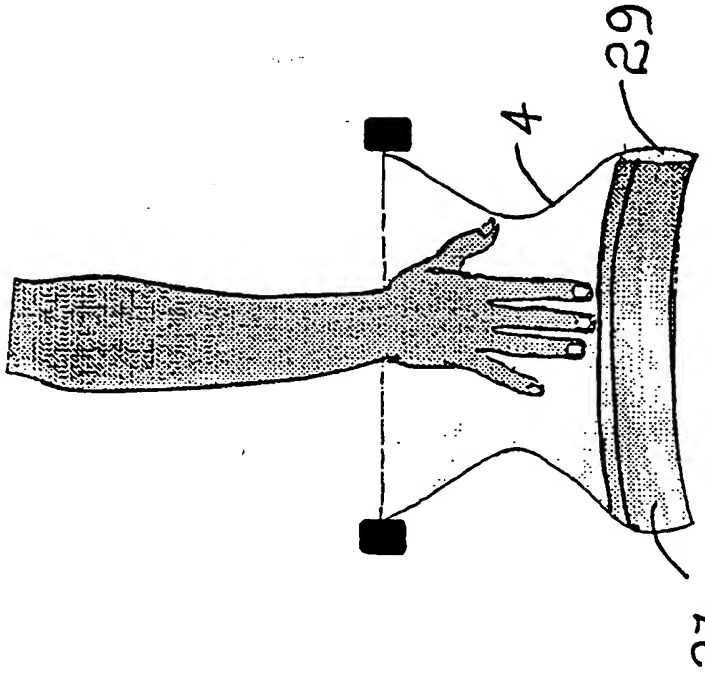

Fig. 6

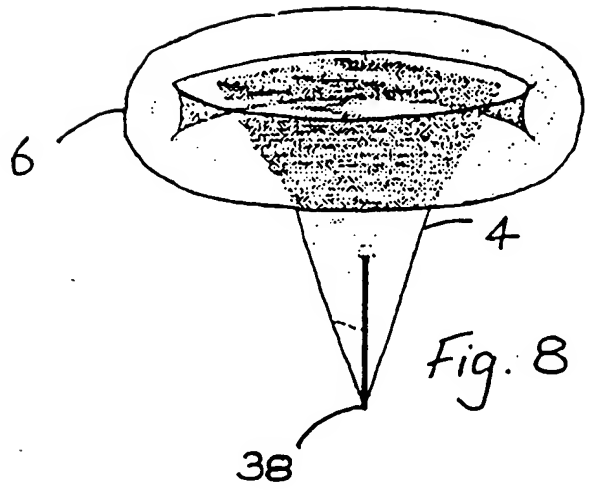

Fig. 8

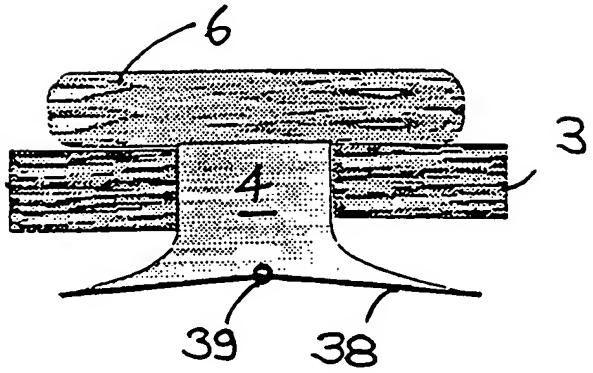

Fig. 9

INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5514133 A	07-05-1996	NONE	
WO 9522289 A	24-08-1995	IE 940150 A	04-10-1995
		IE 940613 A	04-10-1995
		IE 950055 A	07-08-1996
		AT 164303 T	15-04-1998
		AU 695770 B	20-08-1998
		AU 1717395 A	04-09-1995
		BR 9506817 A	09-09-1997
		CA 2183064 A	24-08-1995
		CN 1144471 A	05-03-1997
		CZ 9602404 A	16-04-1997
		DE 69501880 D	30-04-1998
		DE 69501880 T	23-07-1998
		EP 0744922 A	04-12-1996
		EP 0807416 A	19-11-1997
		ES 2115365 T	16-06-1998
		FI 963226 A	17-10-1996
		HU 76016 A,B	30-06-1997
		JP 9509079 T	16-09-1997
		NO 963421 A	14-10-1996
		NZ 279907 A	26-06-1998
		PL 315939 A	09-12-1996
		RU 2137453 C	20-09-1999
		US 5803921 A	08-09-1998
		ZA 9501378 A	24-10-1995
WO 9636283 A	21-11-1996	US 5634937 A	03-06-1997
		US 5964781 A	12-10-1999
GB 2275420 A	31-08-1994	NONE	
US 5366478 A	22-11-1994	NONE	
US 5741298 A	21-04-1998	US 5947922 A	07-09-1999
WO 9507056 A	16-03-1995	AT 188364 T	15-01-2000
		AU 696289 B	03-09-1998
		AU 7507494 A	27-03-1995
		CA 2171177 A	16-03-1995
		DE 69422530 D	10-02-2000
		EP 0776180 A	04-06-1997
		EP 0834279 A	08-04-1998
		EP 0888755 A	07-01-1999
		EP 0887047 A	30-12-1998
		EP 0887048 A	30-12-1998
		ES 2142404 T	16-04-2000
		JP 9502624 T	18-03-1997
US 5524644 A	11-06-1996	NONE	

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 5 366 478 A (CANDADAI RAMESH S ET AL) 22 November 1994 (1994-11-22) abstract; figures 1,2	1
A	US 5 741 298 A (MACLEOD CATHEL) 21 April 1998 (1998-04-21) column 8, line 61 - line 67; figure 2	9
A	WO 95 07056 A (ENCORET) 16 March 1995 (1995-03-16) cited in the application abstract; figure 9	1
A	US 5 524 644 A (CROOK BERWYN M) 11 June 1996 (1996-06-11) abstract; figures 1-6	8

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34

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X Y	US 5 514 133 A (STEIN H DAVID ET AL) 7 May 1996 (1996-05-07) column 3, line 61 -column 5, line 14; figures 1-5	1,2,7-9 3-6
Y	WO 95 22289 A (BONADIO FRANK ;GAYA LTD (IE)) 24 August 1995 (1995-08-24) page 20, line 24 -page 21, line 21; figures 14,15	3-6
X	WO 96 36283 A (GEN SURGICAL INNOVATIONS INC) 21 November 1996 (1996-11-21) page 13, line 19 -page 15, line 15; figure 12	1,2,6,7
X	GB 2 275 420 A (GAUNT) 31 August 1994 (1994-08-31) abstract; figures 3,10	1

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